# EXHIBIT 6



## THE COURT STATES OF ANDREOS

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#### UNITED STATES DEPARTMENT OF COMMERCE

**United States Patent and Trademark Office** 

April 08, 2024

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APPLICATION NUMBER: 15/262,818 FILING DATE: September 12, 2016 PATENT NUMBER: 10561808 ISSUE DATE: February 18, 2020



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VIA EFS

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Declan Walsh et al.

Conf. No.: 1099 Group Art Unit: 2876

Appln. No.: 15/262,818 Examiner: Daniel A. Hess

September 12, 2016 Attorney Docket No.: 026723-5043-US-15 Filing Date:

Title: DOSE COUNTER FOR INHALER HAVING AN ANTI-REVERSE ROTATION

**ACTUATOR** 

#### Response to the Office Action

The following Response is submitted in response to the Office Action dated December 16, 2016 (Paper no. 20161212). No extension of time fee is due as this Response is being timely filed on or before the initial deadline of March 16, 2016.

Except for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310 (Billing No. 026723-5043-US-15).

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#### LISTING OF THE CLAIMS

What is claimed is:

- 1. (Original) A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.
- 2. (Original) The dose counter as claimed in Claim 1 in which the counter display comprises a tape.
- 3. (Original) The dose counter as claimed in Claim 2 in which the tape has dose counter indicia displayed thereon.
- 4. (Original) The dose counter as claimed in Claim 2 wherein the first station comprises a first shaft, the tape being arranged on the first shaft and to unwind therefrom upon movement of the counter display.
- 5. (Original) The dose counter as claimed in Claim 4 in which the first shaft is mounted for rotation relative to a substantially rotationally fixed element of the dose counter.
- 6. (Original) The dose counter as claimed in Claim 5 in which the regulator comprises at least one projection on one of the first shaft and the substantially rotationally fixed element, which is arranged to engage incrementally with one or more formations on the other of the substantially rotationally fixed element and the first shaft.
- 7. (Original) The dose counter as claimed in Claim 6 in which at least two said projections are provided.

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- 8. (Original) The dose counter as claimed in Claim 6 in which exactly two said projections are provided.
- 9. (Original) The dose counter as claimed in Claim 6 in which each projection comprises a radiused surface.
- 10. (Original) The dose counter as claimed in Claim 6 in which the at least one projection is located on the substantially rotationally fixed element which comprises a fixed shaft which is fixed to the main body of the dose counter, the first shaft being rotationally mounted to the fixed shaft.
- 11. (Original) The dose counter as claimed in Claim 10 in which the fixed shaft has at least two flexible legs, and each leg has at least one said projection formed in an outwardly facing direction thereon, said one or more formations being formed on an inwardly facing engagement surface of the first shaft, said at least one projection being arranged to resiliently engage said one or more formations.
- 12. (Original) The dose counter as claimed in Claim 6 in which a series of said formations are provided.
- 13. (Original) The dose counter as claimed in Claim 6 in which an even number of said formations is provided.
- 14. (Original) The dose counter as claimed in Claim 6 in which from eight to twelve of said formations are provided.
- 15. (Original) The dose counter as claimed in Claim 14 in which ten of said formations are provided.
- 16. (Original) The dose counter as claimed in Claim 6 in which each said formation comprises a concavity formed on an engagement surface.

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- 17. (Original) The dose counter as claimed in Claim 16 in which each concavity comprises a radiused surface wall portion which merges on at least one side thereof into a flat wall portion surface.
- 18. (Original) The dose counter as claimed in Claim 17 in which the engagement surface includes a series of said concavities and in which convex wall portions of the engagement surface are formed between each adjacent two said concavities, each said convex wall portion comprising a convex radiused wall portion.
- 19. (Original) The dose counter as claimed in Claim 18 in which each convex radiused wall portion of each convex wall portion is connected by said flat wall portion surfaces to each concavity which is adjacent thereto.
- 20. (Original) The dose counter as claimed in Claim 10 in which the fixed shaft comprises a split pin with fork legs and in which each projection is located on a said fork leg.
- 21. (Original) The dose counter as claimed in Claim 4 in which the first shaft comprises a substantially hollow bobbin.
- 22. (Original) The dose counter as claimed in Claim 21 in which said one or more formations are located on an inner surface of the bobbin.
- 23. (Original) The dose counter as claimed in Claim 4 wherein the drive system comprises a tooth ratchet wheel arranged to act upon a second shaft which is located at the second station, the second shaft being rotatable to wind the tape onto the second shaft.
- 24. (Original) The dose counter as claimed in Claim 23 in which the second shaft is located on the main body of the dose counter spaced from and parallel to the first shaft.

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- 25. (Original) The dose counter as claimed in Claim 23 in which the tooth ratchet wheel is fixed to the second shaft and is arranged to rotate therewith.
- 26. (Original) The dose counter as claimed in Claim 23 which includes an anti-back drive system which is arranged to restrict motion of the second shaft in a tape winding direction.
- 27. (Original) The dose counter as claimed in Claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display.
- 28. (Original) The dose counter as claimed in Claim 27 in which the resistance force is greater than 0.3 N.
- 29. (Original) The dose counter as claimed in Claim 27 in which the resistance force is from 0.3 to 0.4 N.

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#### **REMARKS**

1. Claims 1-29 are currently pending in the application. No claims have been cancelled or amended. Thus, no new matter has been added.

#### Telephone Interview Request

2. If the Examiner does not consider the claims as presented to be allowable, Applicant respectfully requests a telephone interview with the Examiner. Applicant respectfully requests that the Examiner contact Applicant's attorney Mario Milano at 215-963-5909 to schedule a telephone interview regarding the following remarks before taking further action.

#### Claim Rejections - 35 U.S.C. § 102

3. The Examiner rejected claims 1-13, 16, and 20-26 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent Application Publication No. 2002/0078950 to O'Leary ("O'Leary"). Applicant respectfully traverses this rejection without acquiescing to the Examiner's characterization of the cited references or the pending claims.

Claim 1 of the present application recites:

A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

[Underlining added for emphasis]

Applicant respectfully submits that O'Leary does not disclose or suggest each and every element of independent claim 1. In rejecting claim 1, the Examiner stated that O'Leary discloses

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a regulator and that O'Leary describes a "bobbin shaft 142 is preferably forked and includes radially nubs 146 for creating resilient resistance to rotation of the bobbin 132 on the shaft 142." Office Action, page 3 citing O'Leary ¶ [0057]. The Examiner compares the shape of the forked bobbin shaft 142 of O'Leary with its nubs 146 against the shape of the corresponding hollow inner opening of the bobbin 132 and says it is clear that the nubs 146 will tend to nestle in the concave corners of the inner hexagon and flexibly resist movements from one corner to the next. Office Action, page 3.

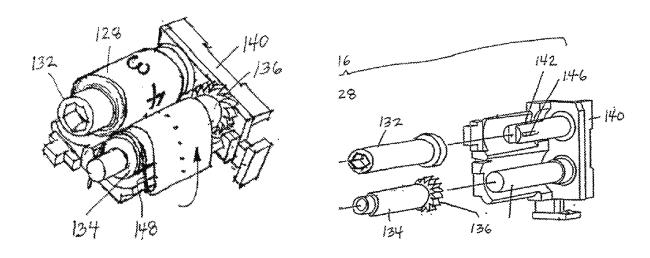


Fig. 14 of O'Leary

Partial view of Fig. 15 of O'Leary

Applicant respectfully submits that O'Leary is silent as to the bobbin shaft 142 extending into the inner hexagon as alleged by the Examiner. As shown in Fig. 14 and 15 of O'Leary, reproduced above, full depth of the hexagonal hollow referred to by the Examiner is visible. Thus, Applicant respectfully submits that the hexagonal hollow illustrated in Fig. 14 of O'Leary does not extend the full length of the bobbin 132. The nubs 146 of O'Leary are axially spaced from the forked end of the shaft 142 as shown in Fig. 15. Applicant respectfully submits that the nubs 146 illustrated in Fig. 15 of O'Leary are not shown as extending into the inner hexagon as alleged by the Examiner. Neither the nubs 146, nor the forked end of the shaft 142, are visible within the hexagon of Fig. 14 of O'Leary and O'Leary fails to disclose such positioning of the nubs. Furthermore, O'Leary merely states that the radial nubs 146 create resilient rotation of the bobbin 132 on the shaft 142. O'Leary is silent as to a regulator which regulates motion of the

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counter display at the first station to <u>incremental movements</u> as recited in claim 1. Thus, Applicant respectfully submits that O'Leary does not disclose the device of claim 1.

Claims 2-13, 16, and 20-26 depend upon claim 1 and are patentable over O'Leary for at least the same reasons. Reconsideration and withdrawal of any rejection of claims 1-13, 16, and 20-26 are respectfully requested.

#### Claim Rejections – 35 U.S.C. § 103

4. The Examiner rejected claims 14-15, 17, and 27-29 under 35 U.S.C. § 103(a) as unpatentable over O'Leary. Claims 14-15, 17, and 27-29 depend upon claim 1 and are patentable over the cited references for at least the same reasons as discussed above. Based at least upon the above, Applicant respectfully requests that the Examiner reconsider and withdraw any rejection of claims 14-15, 17, and 27-29.

#### Allowable Subject Matter

5. The Examiner indicated that claims 18-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten into independent form including all of the limitations of the base claim and any intervening claims.

Applicant thanks the Examiner for indicating that claims 18-19 include allowable subject matter but decline to rewrite the claims in independent form at this time in view of the argument presented above.

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#### **CONCLUSION**

6. Each and every ground of each rejection in the outstanding office action has been addressed herein. To the extent a particular argument in support of a rejection by the Examiner is not expressly addressed, that argument is most in view of the foregoing and Applicant does not acquiesce to any such argument or the Examiner's characterization of the cited references.

In view of the foregoing remarks, Applicant respectfully submits that the present application, including claims 1-29, is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

Date: March 15, 2017 By: /Mario T. Milano/

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